

Isabel Filipa Ribeiro Poleri

Incidence and characteristics of type B aortic dissection - a single center series

Incidência e características da disseção da aorta tipo B – um estudo unicêntrico

março, 2018

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Mestrado Integrado em Medicina

Área: Cirurgia Vascular

Tipologia: Dissertação

Trabalho efetuado sob a Orientação de:

Professor Doutor Sérgio Manuel Moreira Sampaio

Trabalho organizado de acordo com as normas da revista:

Sociedade Portuguesa de Cirurgia Cardiotorácica e Vascular

março, 2018

FMUP

Eu, Isabel Filipa Ribeiro Poleri, abaixo assinado, nº mecanográfico 201206626, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro ter atuado com absoluta integridade na elaboração deste projeto de opção.

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Faculdade de Medicina da Universidade do Porto, 21/03/2018

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Cirurgia Vascular

TÍTULO DISSERTAÇÃO/MONOGRRAFIA (riscar o que não interessa)

Incidence and characteristics of type B aortic dissection - a single center series

ORIENTADOR

Professor Doutor Sérgio Manuel Monteiro Sampaio

COORDINADOR (se aplicável)

ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTES TRABALHOS APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	<input type="checkbox"/>
É AUTORIZADA A REPRODUÇÃO PARCIAL DESTES TRABALHOS (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	<input type="checkbox"/>
DE ACORDO COM A LEGISLAÇÃO EM VIGOR, (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) NÃO É PERMITIDA A REPRODUÇÃO DE QUALQUER PARTE DESTES TRABALHOS.	<input checked="" type="checkbox"/>

Faculdade de Medicina da Universidade do Porto, 21/03/2012

Assinatura conforme cartão de identificação: Isabel Filipe Ribeiro Poleri

Incidence and characteristics of type B aortic dissection - a single center series

Authors

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Manuscript presented at “Congresso SPCCTV 4D VISIONS 17” (24th to 26th November 2017)

Word count: 3027

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Abstract

Background: Type B aortic dissection (TBAD) estimated annual incidence is between 2.9 and 4.0 per 100,000. DISSECT classification aims to reunite clinical and anatomical characteristics of interest to clinicians involved in its management. The aim of this paper is to describe the reality of a tertiary institution with a referral area of 0.7 million inhabitants.

Methods: This is a retrospective study that included all patients with TBAD admitted to hospital from march 2006 to the end of 2016. The computerized tomographic angiography that enabled the TBAD diagnosis was classified using DISSECT classification.

Results: Thirty-two patients were included, setting up a TBAD incidence of approximately 0.6 per 100,000 per year. As to DISSECT classification, 79.3% were acute (Duration), 66% had a primary Intimal tear location in aortic arch, the maximum trans-aortic diameter was 44 ± 13 mm (Size), 60% extended from aortic arch to abdomen or iliac arteries (Segmental Extent), 28% presented with Complications, and 28% had partial Thrombosis of false lumen. Six patients underwent surgery. At 12 months, overall survival was $67.2\pm 9.1\%$ and survival free of aorta-related mortality was $74\pm 8.9\%$. Survival free of aortic dilatation was $54.4\pm 10.3\%$. In univariate analysis, the presence of complications and chronic kidney disease associated with increased overall and aorta-related mortality rates. Hypertension was associated with aortic dilatation.

Conclusions: The incidence verified was lower than what has been described in literature. DISSECT classification can be easily applied to TBAD cases. The presence of

complications, chronic kidney disease and hypertension were identified as prognostic determinants.

Introduction

Type B aortic dissection (TBAD) consists on a tear of the aorta inner lining of aorta, causing the presence of a false lumen that allows blood circulation on the media layer[1]. Stanford classification divides this pathology, based on anatomic criteria, in type A aortic dissection, which involves the ascending aorta, and TBAD, which originates distally to the left subclavian artery, thus involving the descending aorta[2]. TBAD corresponds to 40% of all aortic dissections and has an estimated incidence between 2.9 and 3.5 per 100000. This condition is associated with high morbidity and mortality[3-5]. It affects mostly men between the ages of 60 and 65 [1, 6]. The classic presentation consists in sudden and intense chest and interscapular pain associated with hypertension[3, 7]. In fact, although the etiology of TBAD is multifactorial, hypertension is an important risk factor and it can be found in 80% of cases [1, 8]. The clinical management of this patients has been highly controversial mainly since the development of endovascular techniques that allow the repair of the dissected aorta in a less invasive way than open surgery [9]. The patients with complicated TBAD (malperfusion syndrome, aortic rupture, aneurismal dilatation, proximal or distal progression of the dissection, refractory pain and refractory hypertension) – about 20%, were classically treated with thoracotomy. However, European Society of Cardiology now recommends primary treatment with endovascular approach [1, 5, 10]. The new guidelines of European Society for Vascular Surgery also recommend this approach [7].

The management of uncomplicated TBAD is more complex. The classic treatment consists on pharmacologic management with antihypertensive drugs, being beta-blockers the first line choice[6, 8]. However, the advance of thoracic endovascular aortic repair (TEVAR) has motivated its use as an alternative to the treatment of uncomplicated TBAD. There are two randomized trials that evaluate the possibility of using

endovascular methods as first line therapy: the INSTEAD-XL (Investigation of Stent Grafts in Aortic Dissection with extended follow-up) trial concluded that TEVAR in addition to best medical treatment allowed a 5-year improvement in aorta-related mortality [10]; the ADSORB (Acute Dissection Stentgraft OR Best Medical Treatment) trial [11] demonstrated, after a year of follow up, that TEVAR in addition to best medical treatment, is safe and is related with aortic remodeling, false lumen thrombosis and reduction of its diameter when compared with best medical treatment alone[11].

The natural history of uncomplicated TBAD and, especially, the benefit of a more interventional strategy is yet to be clarified. Thus, the evaluation of patients with TBAD treated with the different available modalities is needed.

The aim of this paper is to characterize the cohort of all patients admitted for type B aortic dissection in a tertiary institution. This will enable the evaluation of the incidence of the disease and verify if it follows what is described in the literature.

Methods

This paper consists on a retrospective study that included all patients with TBAD admitted on Centro Hospitalar de São João, with a referral area of about 0.7 million habitants, in the period from march of 2006 to the end of 2016.

The sample was obtained from the analysis of all patients codified with aortic dissection in ICD10 (4441 – Aneurysm and Aortic Dissection; 44100 - Aortic Dissecting Aneurysm, site non-specified; 44101 – Thoracic Aortic Dissecting Aneurysm; 44102 – Abdominal Aortic Dissecting Aneurysm; 44103 – Thoraco-abdominal Aortic Dissecting Aneurysm). Demographic characteristics, comorbidities such as diabetes, hypertension, hyperlipidemia, carotid disease, coronary disease, chronic kidney disease, pulmonary

disease, heart failure, history of coronary treatment (percutaneous transluminal coronary angioplasty and coronary artery bypass surgery), peripheral artery disease, history of heart surgery and usual medication of all patients were collected from clinical registries. For each patient, the computerized tomographic (CT) angiography that enabled the TBAD diagnosis was classified using the DISSECT classification. The date of this CT scan was considered the inclusion date of these patients. The DISSECT classification, proposed by M.D.Dake[12], is a new mnemonic based approach on the evaluation of aortic dissections that aims at standardizing the imaging and clinical classification of these patients. This classification includes the analysis of six variables that influence the therapeutic decision **D**uration of dissection, (primary) **I**ntimal tear location within the aorta, **S**ize based on the maximum trans-aortic diameter (true lumen), aortic involvement **S**egmental extent from proximal to distal boundary, **C**linical complications related to dissection and aortic false lumen **T**hrombosis.

The primary outcomes of this paper were defined as overall mortality, aorta-related mortality and aortic dilatation. The need for aortic surgery after TBAD diagnosis was also analyzed.

The statistical analyses were performed using SPSS software. Continuous variables were expressed as mean \pm standard deviation (SD) when normally distributed and as median and interquartile range (IQR) when skewed. Categorical variables were presented as percentages. Overall mortality rates and aorta-related mortality rates were estimated using Kaplan-Meier method. Mantel-Cox analyses was used to study determinants of mortality and aortic dilatation.

Funds

No funds were required to perform this analyzes.

Results

We included 32 patients, ascertaining a TBAD incidence of approximately 0.6 per 100000 in the last 10 years. Demographic and clinical characteristics of this patients are showed in Table 1. The majority were men (84%) with a mean age of 60 ± 13 years; 84% were hypertense, 46% were ex-smokers or active smokers and 13% had diabetes.

DISSECT classification

As to DISSECT classification, 79.3% were acute (**D**uration), 66% had an Intimal tear (primary) location in the aortic arch, the maximum trans-aortic diameter was 44 ± 13 mm (**S**ize), 60% extended from aortic arch to abdomen or iliac arteries (**S**egmental extent), 28% presented with **C**omplications, being rupture and branch vessel malperfusion the most frequent, and 28% had partial false lumen **T**hrombosis (versus 66% with permeability of false lumen). DISSECT classification is represented in table 2.

Aortic Intervention

Six patients underwent surgery, 3 of them in acute phase, 1 of them in subacute phase and 2 of them in chronic phase. All patients that underwent surgery in acute and subacute phase did so due to complications of TBAD, being either branch vessel malperfusion (1 of them) or aortic rupture (3 of them). The reasons for aortic intervention and respective procedure are specified in Table 3.

Mortality

At 12 months, overall survival of this series was $67.2\pm 9.1\%$ and survival free of aorta-related mortality was $74.4\pm 8.9\%$ (Figure 1 A and B). Mortality causes are reported in table 4. At 12 months, survival free of aortic dilatation was $54.4\pm 10.3\%$ (Figure 1 C).

Table 4 discriminates the causes of mortality of each patient and the time between the inclusion and death of each of them.

Mantel-Cox analyses identified the presence of complications and chronic kidney disease as risk factors of overall mortality and aorta-related mortality. Hypertension was identified as a risk factor of aortic dilatation. No significant differences were found in the remaining groups. Univariate analyses for predictors of overall mortality, aorta-related mortality and aortic dilatation are showed in Table 5.

Discussion

The verified incidence of TBAD was lower than what has been reported in literature (0.6 per 100000 vs 2.5 to 3.9 per 100000)[3]. The sample was obtained from the analyses of the patients codified with dissection and patients codified with aortic aneurismal disease. There is no codification that corresponds directly to patients with TBAD. Therefore, a possible explanation for this low incidence of the disease may be the miscoding of patients with this pathology. In addition, an elevated number of the patients analyzed on preliminary phase did not presented with CT scan and, therefore, were not included in this study since this diagnose could not be confirmed. This may explain a possible sub representation of patients with TBAD in this sample. The low incidence may also reflect less disease in the population studied.

The CT scans of this patients were evaluated with DISSECT classification. Classically, two classifications based mostly on anatomic characteristics were used, DeBakey classification [13], proposed in 1965, and Stanford classification[2], proposed in 1970. Both of these methods are based in aorta imaging and allow the division of the patients in two groups: those who will benefit from surgical treatment and those who will be submitted to medical treatment alone. However, these classifications do not consider the

current guidelines for the treatment of TBAD, in which endovascular techniques may play an important role. In this decision, factors such as duration of the disease, presence of complications or false lumen thrombosis need to be considered and the previously referred classic methods do not take them into account. Therefore, the DISSECT classification, proposed by M.D. Dake and published in 2013, a mnemonic based method, is easy to apply and takes into consideration a group of characteristics of interest in contemporary therapeutic decision of patients with aortic dissection, particularly those with TBAD. This classification allows an easy interaction between anatomical and clinical aspects that are relevant to assist the decision of contemporary treatment of patients with TBAD, in which endovascular techniques are emerging [12].

Our univariate analyses showed the presence of complications and chronic kidney disease as risk factors of overall mortality and aorta-related mortality. Hypertension was identified as a risk factor of aortic dilatation. Some independent risk factors for mortality in TBAD have been described in literature (Table 6), such as age and some other clinical co-morbidities, as acute renal failure, coronary heart disease or pulmonary disease as independent predictors of mortality [4, 14-20].

The classic treatment for non-complicated TBAD consists on pharmacologic managing with antihypertensive drugs, being beta-blockers the first line choice as the best medical treatment[14], but the overall survival of the patients treated with the best medical treatment can be as low as 50%, at 5 years,[11] and the estimated rate of rupture is about 56% when aortic lumen is over 60mm, also at 5 years[21]. New trends in the treatment of patients with TBAD show endovascular techniques as an option for the treatment of these patients. There are two randomized trials that compare the two therapeutic options. Nienaber et al., in INSTEAD-XL trial [10], randomized 72 for treatment with TEVAR plus best medical treatment and 68 patients for best medical treatment alone. The results

showed that TEVAR is associated to a lower aortic related mortality at 5 years follow-up ($6.9\pm 3.0\%$ with TEVAR, and $19.3\pm 4.8\%$ with best medical treatment). Furthermore, TEVAR was associated with a greater expansion of the true lumen and greater decrease in false lumen when compared with medical treatment alone and complete false lumen thrombosis was found in 90.6% of the patients. On the other hand, with medical treatment the false lumen thrombosis was only 22% and aortic expansion was seen in 66% of the patients (vs 20.8% with TEVAR).

As in INSTEAD-XL, Brunkwall et al., in the ADSORB trial [11] randomized 30 patients for treatment with TEVAR and 31 for best medical treatment alone. They also verified a greater expansion of true lumen and greater decrease of false lumen with TEVAR rather than with best medical treatment alone. Moreover, false lumen thrombosis was not found in 97% of the patients with medical treatment vs 13% with TEVAR. Thereby, these trials show benefit in the use of endovascular treatment with decreased mortality due to beneficial effects on aortic remodeling and thrombosis in the false lumen. In this study, however, none of the patients with non-complicated TBAD were submitted to endovascular treatment.

Other studies have been carried to evaluate prognosis determinants in non-complicated TBAD to, perhaps, determinate the patients that would benefit from an endovascular procedure as first line therapy. Schwartz et al, evaluated 254 patients with medical treatment and concluded that an aortic diameter $>40\text{mm}$, an entry tear $>10\text{mm}$ and patency of true lumen are associated with an increased risk of subsequent aortic intervention and recommend treatment with TEVAR in these cases [22]. Also, a false lumen $>22\text{mm}$ and an aortic diameter $>44\text{mm}$ are predictors of intervention [18]. A new study, conducted by Sailer et al[23], demonstrates that the presence of connective tissue disease and 4 morphological features identified by CT scan (false lumen circumferential

coverage, maximum aortic diameter, false lumen outflow volume and number of intercostals arteries) are associated with late adverse events. Thereby, they developed a risk-prediction internally validated model that allows to calculate the individual risk of adverse events after an initially uncomplicated TBAD, identifying patients who would benefit of an endovascular intervention at an early stage. Thus, recent literature suggests that uncomplicated TBAD treated with TEVAR is associated with lower aortic remodeling and lower mortality, promoting its use, especially in patients that have predictors of later intervention or adverse prognosis.

Conclusion

TBAD is an entity whose best approach to patients is yet to be clarified. DISSECT classification can help in decision making of the treatment of these patients. New trends in the treatment of patients with TBAD show endovascular techniques as a viable option for their treatment, especially in those which clinical and anatomic characteristics predicts later intervention. Notwithstanding, further studies are needed to characterize TBAD in Portugal.

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Table 1 - Demographic characteristics and comorbidities of 32 patients with type B aortic dissection.

	No. or mean	%
Gender		
Male	27	84.4
Female	5	15.6
Age	60.34±12.69	
Tobaco		
No	14	53.8
Ex-smoker	5	19.2
Smoker	7	26.9
Diabetes Mellitus		
No	28	87.5
Diet or oral medication controlled	13	9.4
Insulin dependent	1	3.1
Hyperthension		
No	5	15.6
Regulated by monotherapy	25	78.1
Regulated by 2 drugs	2	6.3
Regulated by > 2 drugs	0	0.0
Carotid disease		
No	28	87.5
Assymtomatic significant stenosis	0	0.0
History of transient ischemic attack	1	3.1
Ischemic stroke	3	9.4
Cornorary disease		
No	29	90.6
Stable Angina	0	0.0
Unstable Angina	0	0.0
MI > 1 year	0	0.0
MI <1 year	3	9.4
Chronic kidney disease		
No	21	65.6
Mild increased serum creatinine <210µmol/L	7	21.9
Severe increased serum creatinine 220-250µmol/L	2	6.3
Serum creatinine >250µmol/L or dialysis/kidney transplantation dependent)	2	6.3

Table 2 – Complications in type B aortic dissection patients.

	No. or mean	%
Duration		
Acute - < 2 weeks from onset of symptoms	23	79.3
Subacute - 2 weeks to 3 months after symptom onset	1	3.4
Chronic - > 3 months from initial symptoms	5	17.2
Intimal tear location		
Ascending aorta	0	0.0
Aortic arch	21	65.6
Descending aorta	11	34.4
Abdominal aorta	0	0.0
Unknwon	0	0.0
Aortic size	22.69±10.81	
maximum trans-aortic diameter	43.73±13.24	
Segmental extent		
Aortic Arch to Abdominal Aorta	10	30.3
Aortic Arch to Iliac	11	33.3
Descending exclusively	5	15.2
Descending to abdominal Aorta	1	3.0
Descending to iliac	5	15.2
Complications		
Aortic valve involvement	0	0.0
Cardiac tamponade	1	3.1
Rupture	5	15.6
Branch vessel malperfusion	3	9.4
Progression of aortic involvement with proximal or distal extension of dissection	0	0.0
Other	0	0.0
None	23	71.9
False lumen thrombosis		
Patent aortic false lumen	21	65.6
Complete thrombosis	2	6.3
False thrombosis	9	28.1

Table 3 - Reasons for aortic intervention and respective procedure.

Time between inclusion and aortic surgery	Reason for intervention	Type of aortic intervention
2 days	Branch vessel malperfusion	TEVAR
6 days	Aortic rupture	TEVAR
9 days	Aortic rupture	TEVAR
18 days	Aortic rupture	Intra-abdominal vascular shunt or bypass
1173 days	Aortic valve insufficiency and ascending aorta aneurysm	Aortic valvuloplasty
2511 days	Abdominal aorta aneurysm	TEVAR

Table 4 - Causes of mortality in patients with type B aortic dissection.

Time between inclusion and death	Cause of death
1 day	Ventricular fibrillation
8 days	Aortic rupture
10 days	Aortic rupture
13 days	Aortic rupture
21 days	Aortic rupture
50 days	Aortic rupture
344	Intracerebral hemorrhage
513 days	Septic shock
965 days	Aortic rupture

Table 5 - Univariate analyses for predictors of overall mortality, aorta-related mortality and aortic dilatation.

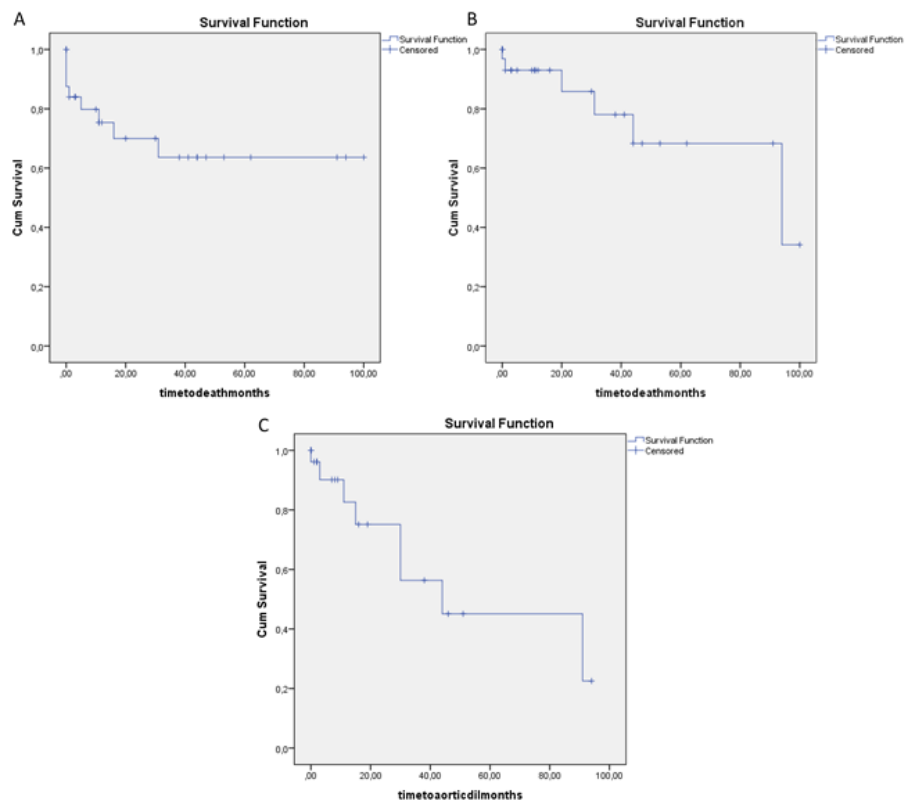
	Overall mortality (P-value)	Aorta-related mortality (P-value)	Aortic dilatation (P-value)
Male gender	0.546	0.546	0.179
Smoker	0.899	0.384	0.728
Diabetes	0.500	0.750	0.210
Hypertension	0.585	0.186	<0.001
Carotid disease	0.575	0.110	0.072
Coronary disease	0.835	0.406	0.637
Chronic Kidney disease	0.002	0.002	0.454
Heart failure	0.749	0.515	0.391
Peripheral arterial disease	0.240	0.703	0.690
Duration of presentation	0.046	0.052	0.469
Intimal tear location	0.276	0.045	0.768
Complications	<0.001	<0.001	0.052
False lumen thrombosis	0.399	0.255	0.955

Table 6 - Predictors of mortality in type B aortic dissection.

Glomer, 1990 [14]	Presenting complication of dissection Age Rupture
Umaña, 2002 [15]	Shock Visceral ischemia Arch extension Rupture Stroke Previous sternotomy Coronary artery disease Pulmonary disease
Suzuki, 2003 [16]	Branch vessel involvement Lack of chest/back pain Hypotension/shock
Tsai, 2006 [17]	Female gender History of prior aortic aneurysm History of atherosclerosis In-hospital renal failure Pleural effusion on chest radiograph In-hospital hypotension/shock
Jonker, 2013 [4]	Age ≥ 70 years Descending aortic diameter ≥ 5.5 cm Hypotension/shock Visceral ischemia Acute renal failure
Ray, 2016 [18]	Aortic diameter >44 mm Age >60 years
Matsushita, 2017[19]	Initial aortic diameter >40 mm False-lumen diameter $>$ true-lumen diameter
Guo, 2017 [20]	Maximum diameter of the affected aorta

Figures Legend

Figure 1 - Overall survival (A), survival free of aorta-related mortality (B) and survival free of aortic dilatation of 32 patients with TBAD (C) at 12 months.



AGRADECIMENTOS

Ao Professor Doutor Sérgio Sampaio, o meu agradecimento pela oportunidade de desenvolvimento deste projeto e por todo o seu auxílio.

À Dra. Marina Dias Neto, o meu profundo obrigada por toda a ajuda, apoio incondicional e disponibilidade mostradas desde o primeiro momento. Pela sua contribuição fundamental para a realização deste trabalho, pelo esforço incansável sempre mostrado e pela confiança em mim e nas minhas capacidades, os meus sinceros agradecimentos. Sem a sua ajuda, não teria sido possível.

Uma palavra de agradecimento ainda à minha família e amigos pelo seu apoio em todas as horas.

ANEXOS

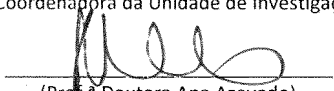
217-17

Unidade de Investigação

Tomei conhecimento. Nada a opor.

07 de Novembro de 2017


A Coordenadora da Unidade de Investigação



(Prof.ª Doutora Ana Azevedo)

DIRECÇÃO CLÍNICA

Aprovado. Ao CA. 8/11/17




(Prof.ª Doutora Ana Azevedo)

AUTORIZADO





CONSELHO DE ADMINISTRAÇÃO DO HOSPITAL DE S. JOÃO 09 NOV 2017

Presidente do Conselho de Administração



(Dr. António Oliveira e Silva)

Director Clínico Enfermeira Diretora Vocal Executivo Vocal Executivo

(Prof. Dr. José Artur Pinheiro) (Dr.ª Patrícia Cardoso) (Dr. Luís Paulo Gomes) (Dr. Rui V. G. Mota)

Exmo. Senhor

Presidente da Comissão de Ética para a Saúde do

Centro Hospitalar de S. João – EPE

Assunto: Pedido de apreciação e parecer para estudo/projecto de investigação

Nome do Investigador Principal: Marina Felicidade Dias Neto

Título do projecto de investigação: Determinantes do prognóstico de doentes com
dissecção aórtica tipo B

Pretendendo realizar no(s) Serviço(s) de Angiologia e Cirurgia Vascular e Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, a sua apreciação e a elaboração do respectivo parecer.

Para o efeito, anexo toda a documentação referida no dossier dessa Comissão respeitante a estudos/projectos de investigação.

Com os melhores cumprimentos.

Porto, 28 / Agosto / 2017

O INVESTIGADOR/PROMOTOR



Comissão de Ética para a Saúde do HSJ
Parecer

Projeto de investigação: “Determinantes do prognóstico de doentes com dissecção aórtica tipo B”.

Promotor:

- Não aplicável.

Conceção e pertinência do estudo

- Trata-se de um estudo retrospectivo a realizar no âmbito da tese de Mestrado Integrado em Medicina na Faculdade de Medicina da Universidade do Porto (FMUP), da aluna Isabel Poleri, sob orientação da Dra. Marina Felicidade Dias Neto, que tem como objetivos principais caracterizar o coorte de todos os doentes admitidos por dissecção aórtica tipo B numa instituição de referência terciária.
- Tem ainda como outros objetivos, avaliar a incidência da doença, verificando se acompanha o que está descrito na literatura bem como determinar factores de prognóstico da doença.
 - Serão incluídos todos os doentes com dissecção aórtica tipo B admitidos no Centro Hospitalar de S. João (CHSJ), no período entre 2006 e 2016.
 - A amostra será obtida a partir da análise da codificação ICD-9.
- Todos os dados a colher de forma anónima são pertinentes e adequados aos objetivos do estudo (dados sócio-demográficos, factores de risco cardiovasculares, clínicos, comorbilidades, antecedentes cirúrgicos e procedimentos cirúrgicos – revascularização coronária, medicação habitual, história de doença arterial periférica, entre outros).
- Para cada doente será analisada a primeira angiotomografia computadorizada (TC) a evidenciar a dissecção e a classificação desta última tem em conta recomendações científicas internacionais.
- O estudo terminará dentro de 6 meses após o seu início e não haverá encargos financeiros para o Centro Hospitalar de S. João (CHSJ).
- O estudo é importante, pertinente e está bem fundamentado.

- A Investigadora Principal, Dra. Marina Felicidade Dias Neto, Médica do internato complementar Angiologia e Cirurgia Vascular do CHSH, dispõe das competências técnica e científica para a realização do estudo.
- O estudo será realizado no Serviço de Angiologia e Cirurgia Vascular do Centro Hospitalar de S. João EPE, que dispõem das condições necessárias para a realização do estudo. O estudo está autorizado pelo Diretor de Serviço, Dr. José Fernando Teixeira.

– Benefício/Risco

- Dada a natureza do estudo retrospectiva não haverá riscos, incómodos ou benefícios para os participantes.

– Respeito pela liberdade e autonomia do sujeito do ensaio

- Dada a natureza retrospectiva do estudo não há necessidade de proceder à obtenção do consentimento informado.

– Confidencialidade dos dados

- A confidencialidade e a privacidade dos dados são garantidas.

– Indemnização por danos

Não aplicável.

– Continuação do tratamento

Não aplicável.

- Propriedade dos dados

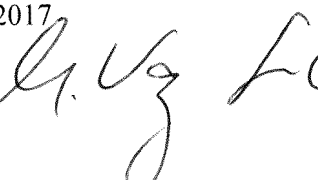
Não aplicável.

Conclusão

Em face da análise do protocolo do estudo “Determinantes do prognóstico de doentes com disseção aórtica tipo B”, proponho a sua aprovação pela CES do HSJ/FMUP.

Porto, 8 de setembro de 2017

O Relator
Prof. Manuel Vaz Silva



7. SEGURO

- a. Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?

SIM ☐ (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)

NÃO ☐

NÃO APLICÁVEL ☒

8. TERMO DE RESPONSABILIDADE

Eu, Marina Felicidade Dias Neto, abaixo-assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsinquia (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo no decurso do actual internamento ou da mesma consulta.

Porto, 17 / Agosto / 2016

Marina F. Dias Neto
O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES
8 de Setembro de 2017

A Comissão de Ética para a Saúde
APROVA por unanimidade o parecer do
Relator, pelo que nada tem a opor à
realização deste projecto de investigação.

[Assinatura]



Normas de Publicação de Trabalhos

A Revista da SPCCTV destina-se à publicação de artigos originais nos campos da Cirurgia Cardiorádica e Vascular. Os manuscritos serão revistos pelos Editores e por revisores externos, e a sua aceitação dependerá do seu interesse, originalidade e validade científicas. A língua oficial da revista é o Português, mas a submissão de Artigos Originais, Artigos de Revisão, Casos Clínicos e Imagens em Cirurgia integralmente em língua Inglesa é fortemente recomendada. Caso desejem, os autores podem enviar uma versão em Inglês (para indexação) e outra em Português, para a revista impressa. E obrigatória a submissão dos resumos em Inglês.

Artigos

São aceites submissões nas seguintes categorias:

Tipo de Artigo	Limite de palavras	Nº Máximo de Autores	Nº Máximo de referências	Nº Máximo de tabelas e figuras
Artigo Original	5000	8	25	8
Artigo de Revisão	s/limite	8	s/limite	s/limite
Caso Clínico	1000	5	10	4
Imagens em Cirurgia	50	4	0	2
Carta ao Editorial	850	4	8	2

Tipo de Artigo	Limite de palavras	Nº Máximo de Autores	Nº Máximo de referências	Nº Máximo de tabelas e figuras
Editorial	1000	2	10	2

A contagem de palavras deve incluir resumo e bibliografia, excluindo legendas e tabelas.

A cada edição, uma imagem seleccionada figura na capa da revista impressa.

Os editoriais apenas podem ser submetido mediante convite do corpo editorial.

As Cartas ao Editor, Imagens em Cirurgia e Editoriais dispensam o envio de Resumo.

Formatação

A submissão devera ser feita integralmente em formato electrónico. Os ficheiros de texto devem ser submetidos em formato Word, com paginas numeradas no canto inferior direito, tipo de letra Times New Roman, tamanho 12, duplo espaço e justificados. As imagens devem ser submetidas em ficheiros individuais, em formato .tiff, com uma definição mínima de 300dpi.

Elementos Obrigatórios

A. Carta de Submissão

Os manuscritos devem ser acompanhados de uma Carta de Submissão que terá de incluir:

- Declaração de originalidade
- Concordância de todos os autores com o teor do artigo e aprovação da versão final
- Transferência da propriedade intelectual para a Revista
- Declaração da presença ou ausência de conflitos de interesse. Se existentes, os Autores devem revelar as relações comerciais com tecnologias em estudo, as fontes de financiamento, a sua filiação Institucional ou Corporativa, incluindo consultadorias.

Nota: Os Autores poderão ser responsabilizados por falsas declarações.

B. Página de Título

Esta deve incluir o Título sem abreviações e em Maiúsculas; o nome e apelido dos autores e o(s) nome(s) e local(ais) da Instituição(ões) de afiliação de cada autor. O nome, endereço, telefone e email do autor correspondente, deve ser inscrito no fundo da página de título. No caso do manuscrito ter sido apresentado nalguma

Reunião, esta deve ser discriminada juntamente com a data de apresentação. A contagem total de palavras do artigo (incluindo os resumos, mas excluindo tabelas, figures e referências) deve ser referida.

C. Resumo (Abstract)

O Resumo, por ser a secção mais lida de todos os artigos, é fundamental. Deve ser factual, sem abreviações (excepto unidades do SI). Deve incluir o Título e Autores, e ser estruturado em Objectivos – problema em estudo ou objectivo do estudo, Métodos, explicando como o estudo foi realizado, Resultados, revelando os dados encontrados e sua importância e Conclusão, revelando a conclusão do estudo. O limite máximo de palavras no resumo é 250.

D. Texto

O texto deve ser organizado nos seguintes elementos:

Introdução: deve revelar o objectivo da investigação e fazer uma revisão bibliográfica curta do estado da arte em relação ao problema em estudo.

Material e Métodos: estes devem ser descritos em detalhe com a informação adequada sobre Estudos Humanos ou Animais como atrás referido. O uso de abreviações deve ser limitado às unidades de medida do SI ou às de uso comum. As tecnologias devem ser nomeadas através do seu nome genérico, com o seu nome comercial, nome e local do fabricante entre parêntesis. As técnicas estatísticas de análise de dados devem ser descritas em detalhe.

Resultados: estes devem ser considerados a parte mais importante do artigo. Por tal, é importante que sejam descritos de forma concisa mas simultaneamente realçando todos os resultados de forma completa, através de tabelas ou figuras, incluindo os comentários dos autores no texto.

Discussão: a discussão, deve ser clara e breve, devendo incluir a interpretação da significância dos resultados e da sua relação com outros trabalhos publicados na mesma área. A importância dos resultados e as limitações metodológicas, se existirem, devem ser enunciadas.

Agradecimentos: a existirem, devem ser referidos no final do texto.

Referências: devem ser apresentadas sequencialmente de acordo com a ordem de uso no texto e apresentadas como números entre parêntesis rectos. Comunicações pessoais e dados não publicados não devem ser incluídos na lista de referências, embora possam ser referidos no texto. Nas referências todos os autores devem ser referidos e os jornais ou revistas apresentados de acordo com as abreviações usadas no Index Medicus. As referências devem ser apresentadas do seguinte modo:

Revistas [1] Dinis da Gama A, Perdígão J, Ministro A, Evangelista A, Damião A, Garcia Alves A. The utilization of the “simplified technique” in the simultaneous

management of independent thoracic and abdominal aortic aneurysms. A clinical report. RevPort Cir Cardiorádica V 2009;3:149-155.

Livros [2] Antunes M J. A Doença da Saúde. Lisboa: Quetzal 2001:167-176. Vários Autores [3] Fragata J, Martins L. Como evitar o erro em Medicina. Em: Fragata J, Martins L, autores. O Erro em Medicina. Lisboa:Almedina, 2008:313-348. Publicações Online (O DOI é referência obrigatória e a única necessária para citações de artigos de publicações online)

Publicações Online (O DOI é referência obrigatória e a única necessária para citações de artigos de publicações online) [4] Azevedo O, Almeida J, Nolasco T, Medeiros R, Casanova J, Bartosch C, Almeida J, Pinho P. Massive right atrial myxoma presenting as syncope and exertional dyspnea: case report. Cardiovascular Ultrasound doi:10.1186/1476-7120-8-23.

E. Tabelas

As tabelas devem ser numeradas de acordo com a sequência de aparecimento no texto, e enviadas num ficheiro conjunto a parte do texto, em formato Word. Devem incluir número e cabeçalho, assim como legenda se necessária.

F. Cabeçalho e Legendas de Figuras

O cabeçalho e legendas de figuras devem ser entregues num ficheiro conjunto a parte do texto, em formato Word, mencionando o número correspondente ao ficheiro de imagem enviado.

G. Figuras

As figuras devem ser numeradas de acordo com a sequência de aparecimento no texto, e enviadas em ficheiros individuais, referenciando o respectivo número. Apenas são aceites ficheiros em formato .tiff com um mínimo de 300dpi.

Submissão Eletrónica

A submissão electrónica de manuscritos deve ser realizada para: manuscritos.revista@spcctv.pt

Apenas são consideradas válidas as submissões que cumpram as regras anteriormente descritas. Após a submissão, os Editores confirmarão a boa recepção do manuscrito junto do autor correspondente.

Manuscritos aceites para revisão

Os manuscritos revistos devem ser enviados convenientemente titulados – revisãol, revisãol2, etc, incluindo novas figures e tabelas caso necessário. Os comentários dos editores e/ou revisores devem ser discutidos ponto a ponto numa carta anexa e as alterações propostas discutidas. As alterações devem ser visíveis utilizando a função “track changes” do Word.

APÊNDICES

Predictors of prognosis in patients with type B aortic dissection

Authors: Marina Dias-Neto, Isabel Poleri, Sérgio Sampaio

Institutions: Department of Angiology and Vascular Surgery, São João Hospital, Porto, Portugal; Faculty of Medicine, University of Porto, Portugal.



Introduction

Type B aortic dissection (TBAD) affects mostly men with an estimated annual incidence between 2.9 and 3.9 per 100,000, appeared to be increasing [1]. DISSECT classification was published in 2013 aiming to reunite clinical and anatomical characteristics of interest to clinicians involved in TBAD management [2]. The clinical management of this patients has been highly controversial, mainly since the development of endovascular techniques. In Portugal, the incidence of the condition, as well as its characteristics and outcomes, are not well documented. The aim of this paper is to describe the reality of a tertiary institution with a referral area of about 0.6 millions habitants.

Methods

This is a **retrospective study** that included all patients with TBAD admitted at São João Hospital Center from 2008 to 2016. The patients were categorized according to their demographic and clinical characteristics collected from clinical registries. For each patient, the computerized tomographic angiography (CTA) scan that enabled the TBAD diagnosis was classified using **DISSECT classification** [2].

The statistical analyses were performed using SPSS software. Continuous demographic variables were expressed as mean \pm standard deviation if they had normal distribution or not, respectively. Categorical variables were presented as percentages. Overall mortality rates and aorta-related mortality rates were estimated using Kaplan-Meier method. Cox regression was used to study determinants of mortality.

Results

Demographic and clinical features

We included **32 patients**, setting up a TBAD incidence of approximately 0.6 per 100,000 in the last 8 years. The majority were men (83%) with a mean age of 60 ± 12 years old; 71% were hypertense, 56% were ex-smokers or active smokers and 13% had diabetes.

DISSECT classification

Table 1- Characteristics of the patients in DISSECT classification.

	No. or mean	%
Duration		
Acute - < 2 weeks from onset of symptoms	22	78,6
Subacute - 2 weeks to 3 months after symptom onset	1	3,6
Chronic - > 3 months from initial symptoms	5	17,9
Intimal tear location		
Ascending aorta	0	0,0
Aortic arch	21	65,6
Descending aorta	11	34,4
Abdominal aorta	0	0,0
Unknwon	0	0,0
Aortic size	22,69 \pm 10,81	
maximum trans-aortic diameter	43,73 \pm 13,24	
Segmental extent		
Aortic to Abdominal	1	3,0
Aortic to Iliac	10	30,3
Descending exclusively	11	33,3
Descending to abdominal	5	15,2
Descending to iliac	1	3,0
	5	15,2
Complications		
Aortic valve involvement	0	0,0
Cardiac tamponade	1	3,1
Rupture	4	12,5
Branch vessel malperfusion	3	9,4
Progression of aortic involvement with proximal or distal extension of dissection	0	0,0
Other	0	0,0
None	24	75,0
False lumen thrombosis		
Patent aortic false lumen	25	65,6
Complete thrombosis	2	6,3
False thrombosis	9	28,1

Aortic intervention

Seven patients underwent surgery, 4 of them in acute phase, 1 in subacute phase and 2 in chronic phase. All patients that underwent surgery in acute and subacute phase were due complications of TBAD, that included branch vessel malperfusion (1 of them) or aortic rupture (4 of them). The patients were submitted to aortic surgery in chronic phase presented aortic dilatation.

Mortality

At 12 months, overall survival of this series was $65,2 \pm 9,0\%$ and survival free from aorta-related mortality was $83 \pm 6,7\%$ (Figure 1 A and B). The presence of complications was identified as an independent risk factor of overall mortality. This was not true to aorta-related mortality.

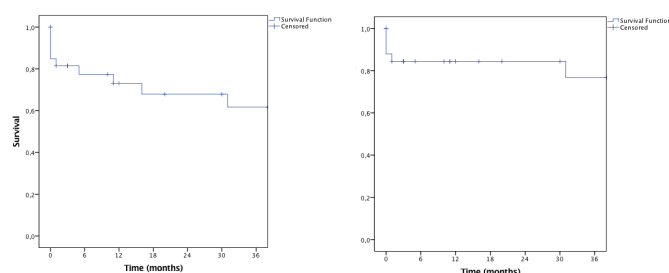


Figure 1 A and B – Overall survival and survival free of aorta related mortality.

Discussion

The verified incidence of TBAD was **lower than what has been reported in literature** (0.6 per 100,000 vs 2.5 to 3.9 per 100,000) [3].

- The sample was obtained from the analysis of the hospital admissions coded with dissection and/or aortic aneurismal disease since there is no codification that corresponds directly patients with TBAD. Therefore, a possible explanation for this low incidence of the disease may be the existence of coding errors of patients with this pathology.

- In addition, an elevated number of the patients analyzed on preliminary phase did not presented with CT scan so they were excluded from this study. This may explain a possible sub representation of patients with TBAD in this sample.

- This low incidence may also be a reflection of lower burden of this disease in the studied population.

The CT scans of this patients were evaluated with **DISSECT classification**.

- DeBakey classification [4] and Stanford classification[5] are classifications of aortic dissection based in aorta imaging, allowing the division of the patients in those who will benefit from surgical treatment or medical treatment alone. These classifications do not consider the current guidelines for the treatment of this patients, in which endovascular techniques play an important role.

- DISSECT classification, proposed by M.D. Dake and published in 2013, a mnemonic based method, is easy to apply and allows an interaction between anatomical and clinical aspects that are relevant to assist the decision of contemporary treatment of patients with TBAD, in which endovascular techniques are emerging [2].

As for predictors of mortality, this study found that the presence of **complications is an independent risk factor of overall mortality**.

- This agrees with what has been described in literature.

- Apart from complications, some studies also showed age and some other clinicals comorbidities such as acute renal failure, coronary heart disease or pulmonary disease as predictors of mortality (4 and 16), Table 2. However, this was not found in our study.

Table 2 - Predictors of mortality in type b aortic dissection.

Glomer, 1990	Presenting complication of dissection	Jonker, 2013	Age ≥ 70 years
	Age	[9]	Descending aortic diameter ≥ 5.5 cm
	Rupture		Hypotension/shock
Umaña, 2002	Shock		Visceral ischemia
[6]	Visceral ischemia		Acute renal failure
	Arch extension	Ray, 2016	Aortic diameter >44 mm
	Rupture	[10]	Age >60 years
	Stroke	Matsushita, 2017	Initial aortic diameter >40 mm
	Previous sternotomy	[11]	False-lumen diameter $>$ true-lumen diameter
	Coronary artery disease		
	Pulmonary disease	Guo, 2017,	Maximum diameter of the affected aorta
Suzuki, 2003	Branch vessel involvement	[12]	
[7]	Lack of chest/back pain		
	Hypotension/shock		
Tsai, 2006	Female gender		
	History of prior aortic aneurysm		
	History of atherosclerosis		
	In-hospital renal failure		
	Pleural effusion on chest radiograph		
	In-hospital hypotension/shock		

The classic treatment for non-complicated TBAD consists on pharmacologic managing with antihypertensive drugs, being beta-blockers the first line choice as the best medical treatment 6. However, new trends in the treatment of patients with TBAD show endovascular techniques as an option for the treatment of this patients. ADSORB trial [13] and INSTEAD-XL trial [14] show benefit in the use of endovascular treatment with decreased mortality due to beneficial effects on aortic remodeling and thrombosis in the false lumen. In this study, however, **none of the patients with non-complicated TBAD were submitted to endovascular treatment**.

Conclusion

TBAD is an entity whose best approach to patients is yet to be clarified. DISSECT classification can help in the decision of the treatment of these patients. Further studies are needed to characterize TBAD in Portugal.

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